

## **REMARKS**

### **I. CHANGES TO THE SPECIFICATION**

In accordance with the Office Action's recommendation, lines 10 and 11 on page 20 of the Specification have been corrected. The Specification has been corrected to state: "Since both ... transducer 42 are ~~slightly~~ greatly modulated or perturbed by a first magnetic flux created by the first coil 48 and ~~greatly~~ slightly modulated by a second magnetic flux created by the second coil 50." No new matter has been introduced to the application by this correction.

### **II. CLAIM OBJECTIONS**

With respect to the Office Action's "claim objections" to Claims 24-29, Applicants submit that the preamble to base claim 24 is consistent with the body of the claim. The preamble of claim 24 is directed to an "apparatus for providing ultrasonic and electromagnetic stimulation to a treatment area." The first element of claim 24 recites "means for generating and propagating a pressure wave towards said treatment area." The Specification discloses that the "combined ultrasonic and E-stim treatment methods and apparatus of the present invention generate and control the spatial distribution of a non-uniform, time varying, directionally-oriented electromagnetic field to produce an ionic current and electric voltage, relative to the spatial and temporal generation and control of a time-varying, directionally-oriented non-uniform acoustic pressure wave, in living tissue." Page 12, lines 10-15 (underlining supplied). The Specification further discloses how ultrasonic and

electromagnetic stimulation can be used to generate and propagate a pressure wave towards a treatment area. Page 12, line 18 – Page 14, line 14. Since both ultrasonic and electromagnetic energy are used to generate and propagate a pressure wave, then the preamble and the body of base claim 24 are not inconsistent, and the body of the base claim correctly pertains to a “pressure wave.”

### III. ANTICIPATION REJECTION

On page 3, the Office Action has rejected claims 1, 2, 6, 8, 9, 10-13, 18, 19, and 23 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,476,438 to Edrich (“the ‘438 patent”). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Claims 1 and 9 have been amended to include the limitation, “at least one ultrasonic transducer and said at least one electromagnetic coil are positioned to focus modulated ultrasound energy toward said treatment area.” (Underlining supplied). Claim 19 has been corrected to omit the phrase “the steps of.” Amended claim 19 already includes a similar limitation, “exciting said at least one electromagnetic coil to create a modulating force to modulate said ultrasonic waves.” (Underlining supplied). Thus, the claimed invention of amended claims 1, 9, and 19 provides focused ultrasound energy modulated by an electromagnetic force. The electromagnetic force modulates the ultrasound energy to provide modulated ultrasound energy to an area or region of tissue. In contrast, the ‘438 patent relates to focusing an electromagnetic force on a relatively small and focused region of tissue.

Col. 2, lines 25-30. An ultrasonic source focuses a set of ultrasound waves through an electromagnetic field causing a localized electromagnetic force to be directed to a relatively small region of tissue such as a single nerve bundle. Thus, the '438 patent relates to merely focusing an electromagnetic force on a relatively small area of tissue, such as a single nerve bundle. The claimed invention differs from the '438 patent since the claimed invention focuses modulated ultrasound energy to a general region of tissue, such as an arm or leg, rather than focusing an electromagnetic force to a specific region of tissue, such as a single nerve bundle. Therefore, the '438 patent does not anticipate amended claims 1, 9, and 19.

Dependent claims 2, 6, 8, 9, 10-13, 18, and 23 are ultimately dependent from either claims 1, 9, or 19, for which arguments of patentability have been advanced above. If each and every element of the independent claims is not anticipated by the '438 patent, then each and every element of the respective dependent claims is not anticipated by the '438 patent.

In the alternative, independent claims 30-32 have now been added, which add limitations to original claims 1, 9, and 19 respectively. The limitations are, "wherein either said at least one ultrasonic transducer or said at least one electromagnetic coil can be selectively biased relative to the other to modulate the energy" or "selectively biasing either said at least one ultrasonic transducer or said at least one electromagnetic coil relative to the other to modulate said ultrasonic waves." These limitations are supported by the Applicants' specification by reference to the various arrangements of ultrasonic transducers and electromagnetic coils shown by at least

FIGs. 5B, 6B, 7B, 8, 9, 10, 11B, and 12B. With respect to FIG. 9, the Specification states that “by changing the position of the electromagnetic coil assembly 44 within the placement module 40, the amount of modulation of the acoustic waves can be controlled ....” p. 20, lines 12-14. Furthermore, with respect to FIGs. 11A to 15A, the Specification states that “the ultrasonic transducer 30 and the electromagnetic coil 32 are positioned differently with respect to each other ....” p. 21, lines 8-9.

The ‘438 patent does not disclose or suggest selectively biasing an ultrasound transducer with respect to an electromagnetic coil, or vice-versa, to modulate energy or ultrasonic waves applied to a treatment area. The Office Action admits that the ‘438 patent does not describe angular positioning of a transducer and coil with respect to each other. FIG. 3 of the ‘438 patent merely shows the fixed, orthogonal orientation of an ultrasonic source (1) with a pair of electromagnetic coils (7). Furthermore, the ‘438 patent is primarily concerned with “focusing” the ultrasound waves on an isolated area approximately 1 cm in diameter orthogonal to the z axis of the main direction of the radiation. Col. 2, lines 1-7. There is no disclosure or suggestion in the ‘438 patent wherein either said at least one ultrasonic transducer or said at least one electromagnetic coil can be selectively biased relative to the other to modulate the energy or ultrasonic waves. Therefore, the ‘438 patent does not anticipate each and every element of newly added claims 30-32, and these claims should be allowable over the cited reference.

#### IV. OBVIOUSNESS REJECTION

On pages 4-5, the Office Action has rejected claims 3-5, 14, 15, and 22 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,476,438 to Edrich (“the ‘438 patent”). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

As discussed above, original claims 1 and 9 have been amended to include the limitation, “at least one ultrasonic transducer and said at least one electromagnetic coil are positioned to focus modulated ultrasound energy toward said treatment area.” (Underlining supplied). Claim 19 has been corrected to omit the phrase “the steps of.” Amended claim 19 already includes a similar limitation, “exciting said at least one electromagnetic coil to create a modulating force to modulate said ultrasonic waves.” (Underlining supplied). The claimed invention of amended claims 1, 9, and 19 provides focused ultrasound energy modulated by an electromagnetic force. The electromagnetic force modulates the ultrasound energy to provide modulated ultrasound energy to an area or region of tissue. In contrast, the ‘438 patent relates to focusing an electromagnetic force on a relatively small and focused region of tissue. Col. 2, lines 25-30. An ultrasonic source focuses a set of ultrasound waves through an electromagnetic field causing a localized electromagnetic force to be directed to a relatively small region of tissue such as a single nerve bundle. Thus, the ‘438 patent relates to merely focusing an electromagnetic force on a relatively small area of tissue, such as a single nerve bundle. The claimed invention differs from the ‘438 patent since the claimed invention focuses modulated ultrasound energy to a general

region of tissue, such as an arm or leg, rather than focusing an electromagnetic force to a specific region of tissue, such as a single nerve bundle. Therefore, the '438 patent does not suggest the limitations of amended claims 1, 9, and 19.

Claims 3-5, 14, 15, and 22 are ultimately dependent from either claims 1, 9, or 19, for which arguments of patentability have been advanced above. Therefore, dependent claims 3-5, 14, 15, and 22 should be allowable over the cited art.

Independent claims 30-32 have now been added, which add limitations to original claims 1, 9, and 19 respectively. The limitations are, "wherein either said at least one ultrasonic transducer or said at least one electromagnetic coil can be selectively biased relative to the other to modulate the energy" or "selectively biasing either said at least one ultrasonic transducer or said at least one electromagnetic coil relative to the other to modulate said ultrasonic waves." These limitations are supported by the Applicants' specification by reference to the various arrangements of ultrasonic transducers and electromagnetic coils shown by at least FIGs. 5B, 6B, 7B, 8, 9, 10, 11B, and 12B. With respect to FIG. 9, the Specification states that "by changing the position of the electromagnetic coil assembly 44 within the placement module 40, the amount of modulation of the acoustic waves can be controlled ...." p. 20, lines 12-14. Furthermore, with respect to FIGs. 11A to 15A, the Specification states that "the ultrasonic transducer 30 and the electromagnetic coil 32 are positioned differently with respect to each other ...." p. 21, lines 8-9.

The '438 patent does not disclose or suggest selectively biasing an ultrasound transducer with respect to an electromagnetic coil, or vice-versa, to modulate energy

or ultrasonic waves applied to a treatment area. The Office Action admits that the '438 patent does not describe angular positioning of a transducer and coil with respect to each other, and further admits that the '438 patent does not explicitly recite the coil wrapped around the placement module or the transducer placed closer to the treatment area than the coil. Rather, the Office Action submits that it would have been obvious to one of ordinary skill in the art at the time of the invention to provide these configurations. However, the '438 patent does not teach or suggest devices or methods "wherein either said at least one ultrasonic transducer or said at least one electromagnetic coil can be selectively biased relative to the other to modulate the energy" or "selectively biasing either said at least one ultrasonic transducer or said at least one electromagnetic coil relative to the other to modulate said ultrasonic waves." Selectively biasing either or both of these components provides a range of treatment options for a user, patient, or health care professional. The '438 patent does not disclose or suggest any other orientation except an orthogonal orientation between the ultrasound source and electromagnetic coils. Therefore, the limitations of newly added claims 30-32 are not suggested by the '438 patent, and these claims should be allowable over the cited art.

Furthermore, on pages 5-6, the Office Action has rejected claims 7, 16, and 21 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,476,438 to Edrich ("the '438 patent") in view of U.S. Patent No. 6,050,943 to Slayton et al. ("the '438 patent"). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Claims 7, 16, and 21 are ultimately dependent from claims 1, 9, or 19, for which arguments of patentability have been advanced above. Therefore, if claims 1, 9, and 19 are in condition for allowance, claims 7, 16, and 21 should also be in condition for allowance.

On page 6, the Office Action has rejected claims 24-29 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,476,438 to Edrich (“the ‘438 patent”) in view of U.S. Patent No. 5,556,372 to Talish (“the ‘372 patent”). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Claims 24-29 are ultimately dependent from claims 1, 9, or 19, for which arguments of patentability have been advanced above. Therefore, if claims 1, 9, and 19 are in condition for allowance, claims 24-29 should also be in condition for allowance.

The Office Action does not reference claims 17 or 20. Since each of these claims depends upon a rejected base independent claim, claims 9 and 19 respectively, then each of claims 17 and 20 are believed to be at least objected to.


Claims 17 and 20 are ultimately dependent from claims 9 and 19, respectively, for which arguments of patentability have been advanced above. Therefore, if claims 9 and 19 are in condition for allowance, claims 17 and 20 should also be in condition for allowance.



**CONCLUSION**

For at least the reasons given above, it is respectfully submitted that amended Claims 1, 9, and 19, and new claims 30-32 define patentable subject matter in view of the amendments and remarks made above. Further, it is respectfully requested that immediate allowance of all the pending Claims 1-32 and notice thereof be issued. Should the Examiner believe that anything further is necessary in order to place the application in better condition for allowance, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below. The Commissioner is hereby authorized to charge any deficiencies or credit any overpayment to Deposit Order Account No. 11-0855.

Respectfully submitted,

  
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